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EXAMINER	
COLBERT, ELLA	

ART UNIT	PAPER NUMBER
3624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/650,482	Applicant(s) STEEN ET AL.	
	Examiner Ella Colbert	Art Unit 3624	MW

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-27 are pending in this communication filed 12/15/03 entered as Response, paper no. 8.

Claim Rejections - 35 USC § 103

2 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson in view of (US 5,924,074) Evans.

With respect to claim 1, Edelson teaches, A pharmaceutical administrative system comprising: a pharmacy network including a pharmacy server and at least one pharmacy client system, the at least one pharmacy client system configured to accept and process orders for medications (col. 7, lines 16-27); and a service center network including a service center server and a service center client system, the service center

network coupled to the pharmacy network and configured with a global database including a plurality of formulary records (col. 7, lines 28-32). Edelson failed to teach, wherein the service center server supplies the pharmacy server at least one of the plurality of formulary records upon request by a pharmacy client system when a order is processed.

Evans teaches, wherein the service center server supplies the pharmacy server at least one of the plurality of formulary records upon request by a pharmacy client system when a order is processed (col. 11, lines 65-67, col. 12, lines 1-15 and lines 56-67, col. 13, lines 1-30, and fig. 24 (406, 408, 410, 414, 416, 418, 430, 432, & 434). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a service center server that supplies the pharmacy server with at least one of the plurality of formulary records upon request by a pharmacy client system when a order is processed and to modify in Edelson because such a modification would allow Edelson to allow a healthcare provider to have easy access to the medication records of the patient.

4. Claims 2-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,737,539) Edelson et al, hereafter Edelson in view of (US 5,845,255) Mayaud.

With respect to claim 2, Edelson teaches, wherein the global database further includes a plurality of order records, each order record including order information for an order accepted and processed by the at least one pharmacy client system (col. 10, lines 5-67 and col. 11, lines 1-4).

With respect to claim 3, Edelson teaches, wherein the global database further includes a plurality of customer records, each customer record including contact and formulary information for at least one customer (col. 14, lines 53-67 and col. 15, lines 1-6).

With respect to claim 4, Edelson teaches, wherein the global database further includes a plurality of patient records, each patient record including contact information and medication history for at least one patient (col. 16, lines 10-35 and col. 19, lines 1-67).

With respect to claim 5, Edelson failed to teach, wherein the pharmacy client system is further configured to generate medication specific label containing medication identification information. Mayaud teaches, wherein the pharmacy client system is further configured to

generate medication specific label containing medication identification information (col. 28, lines 50-67, col. 29, lines 1-65, and fig. 15 (182, 184, 186, & 188). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the pharmacy client system further configured to generate medication specific label containing medication identification information and to modify in Edelson because such a modification would allow Edelson to have the information on the dispensed drugs of a multi-drug prescription into a novel package which has multiple labeled or coded compartments for each of a number of dosing intervals.

With respect to claim 6, Edelson failed to teach, wherein the pharmacy client system is configured to provide updates to the patient, customer, and formulary records in the global database. Mayaud teaches, wherein the pharmacy client system is configured to provide updates to the patient, customer, and formulary records in the global database (col. 31, lines 50-67 and col. 32, lines 1-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the pharmacy client system configured to provide updates to the patient, customer, and formulary records in the global database and to modify in

Edelson because such a modification would allow Edelson to have the prescription creation process, relevant to remote source databases (which may be proprietary) that are updated with appropriate components of the new information and such updates effected with proper controls to ensure data integrity.

With respect to claim 7, Edelson failed to teach, wherein updates to the formulary records include modification to the ingredients of the medication. Mayaud teaches, wherein updates to the formulary records include modification to the ingredients of the medication (col. 36, lines 1-9, col. 35, lines 44-67, and fig. 11 (128 & 130). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have updates to the formulary records include modification to the ingredients of the medication and to modify in Edelson because such a modification would allow Edelson to have formulary information called across a data-retrieval network, each time it is required, from a remote source database the updates are automatically posted across the network.

With respect to claim 8, Edelson and Mayaud failed to teach, wherein updates to the modification to the ingredients of the medication include changes to amounts of caloric content in the medication. Official

Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the modifications to the ingredients of the medication include modifications to electrolytes in the medication because such a modification in Edelson would allow Edelson to have substances that dissociate into two or more ions, to some extent, in water.

With respect to claim 9, this dependent claim is rejected for the similar rationale given above for claim 8.

With respect to claim 10, Edelson failed to teach, wherein the pharmacy client system is configured to verify the updates to the formulary records in the global database. Mayaud teaches, wherein the pharmacy client system is configured to verify the updates to the formulary records in the global database (col. 6, lines 59-67 and col. 7, lines 1-2 and lines 30-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the pharmacy client system is configured to verify the updates to the formulary records in the global database and to modify in Edelson because such a modification would allow Edelson to have a remote database for providing useful information elements to the system.

With respect to claim 11, Edelson and Mayaud failed to teach, wherein the medication specific label is for an intravenous solution and the medication identification information includes a refractive index associated with the intravenous solution. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information about a refractive index of the intravenous solution and to modify in Edelson because such a modification would allow Edelson to have the information regarding the refractive index since the refractive index increases with the atomic number of constituent atoms in the in the intravenous solution.

With respect to claim 12, Edelson and Mayaud failed to teach, wherein the medication specific label is for an intravenous solution and the medication identification information includes a level of potassium associated with the intravenous solution. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific label for an intravenous solution and the medication identification information to include a level of potassium associated with the intravenous solution and to modify

in Edelson because such a modification would allow Edelson to use an intravenous solution for medical conditions such as dehydration to put the electrolytes back into a person's body.

With respect to claim 13, Edelson and Mayaud failed to teach, wherein the pharmacy client system is configured to generate a calcium phosphate solubility curve for an order accepted and processed by the at least one pharmacy client. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the pharmaceutical system wherein the pharmacy client system is configured to generate a calcium phosphate solubility curve for the an order accepted and processed by the at least one pharmacy client and to modify in Edelson because such a modification would provide a time release of the compounds of calcium salts of phosphoric acid which are frequently used as calcium supplements.

With respect to claim 14, Edelson failed to teach, further comprising a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the backup server storing the records replicated in a backup database and providing access to the backup

database by the pharmacy network when the service center network is not available for a predetermined amount of time. Mayaud teaches, further comprising a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the backup server storing the records replicated in a backup database and providing access to the backup database by the pharmacy network when the service center network is not available for a predetermined amount of time (col. 17, lines 44-52, col. 46, lines 16-31, and fig. 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to further comprise a backup network including a backup server, the service center server replicating records of orders for medication and providing the records replicated to the backup server, the backup server storing the records replicated in a backup database and providing access to the backup database by the pharmacy network when the service center network is not available for a predetermined amount of time and to modify in Edelson because such a modification would allow Edelson to have a server system where the file server or database management server manages the data storage over a local area network.

With respect to claim 15, Edelson failed to teach, wherein the pharmacy server is configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network. Mayaud teaches, wherein the pharmacy server is configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network (col. 1, lines 46-67, col. 2, lines 1-11, and col. 6, lines 59-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the pharmacy server configured with a local database containing a subset of formulary records of the plurality of formulary records in the global database that specifically pertains to the pharmacy network and to modify in Edelson because such a modification would allow Edelson to have preferred drugs that vary in content and usually determinative of the cost effectiveness of a prescription in a database.

5. Claims 16-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,758,095) Albaum et al, hereafter Albaum in view

of (US 5,737,539) Edelson et al, hereafter Edelson and further in view of Official Notice.

With respect to claim 16, Albaum teaches, wherein the pharmacy client system comprises: an order maintenance unit configured to create an order for medication for at least one customer and at least one patient (col. 3, lines 3-20); a formulary unit coupled to the order maintenance and presenting information about the medication to the order maintenance unit (col. 3, lines 21-47); a customer unit coupled to the order maintenance unit and presenting information relating to contact and purchasing information for the at least one customer ordering the medication (col. 7, lines 7-24); and a patient unit coupled to the order maintenance unit and the customer unit and presenting information relating to contact and medical information for the at least one patient (col. 10, lines 18-43). Albaum failed to teach, wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication. Edelson teaches, wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication (col. 12, lines 42-65). It would have been obvious to one having ordinary skill in the art at the time

the invention was made to have the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication and to modify in Albaum because such a modification would allow Albaum to have a system that is effectively cognizant of the ongoing prescribing activity.

Albaum teaches, wherein the pharmacy client system comprises: an order maintenance unit configured to create an order for medication for at least one customer and at least one patient (col. 3, lines 3-30); a formulary unit coupled to the order maintenance and presenting information about the medication to the order maintenance unit (col. 3, lines 21-47); a customer unit coupled to the order maintenance unit and presenting information relating to contact and purchasing information for the at least one customer ordering the medication (col. 7, lines 7-24 and col. 10, lines 18-32); and a patient unit coupled to the order maintenance unit and the customer unit and presenting information relating to contact and medical information for the at least one patient (col. 10, lines 33-43); wherein the order maintenance unit is configured to modify the ingredients of the medication and to validate the modifications to the ingredients of the medication (col. 10, lines 44-67).

With respect to claim 17, Albaum teaches, wherein the medication is an intravenous solution (col. 11, lines 60-67 and col. 12, lines 1-3).

With respect to claim 18, Albaum and Edelson failed to teach, wherein the order maintenance unit is configured to validate the modifications to the ingredients by generating a calcium phosphate solubility curve for the medication. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the order maintenance unit configured to validate the modifications to the ingredients by generating a calcium phosphate solubility curve for the medication and to modify in Albaum because such a modification would provide a time release of the compounds of calcium salts of phosphoric acid which are frequently used as calcium supplements.

With respect to claim 19, this dependent claim is rejected for the similar rationale given above for claim 18.

With respect to claim 20, this dependent claim is rejected for the similar rationale given above for claims 18 and 19.

With respect to claim 21, Albaum and Edelson failed to teach, wherein the order maintenance unit is configured to generate medication

specific labels for the medication. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the order maintenance unit configured to generate medication specific labels for the medication and to modify in Albaum because such a modification would allow Albaum to have a prescription delivery system to generate the invoice and label and other documentation prior to delivering the medication to the patient.

With respect to claim 22, Albaum and Edelson failed to teach, wherein the medication specific labels for the medication includes information about a refractive index of the intravenous solution. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information about a refractive index of the intravenous solution and to modify in Albaum because such a modification would allow Albaum to have the information regarding the refractive index since the refractive index increases with the atomic number of constituent atoms in the in the intravenous solution.

With respect to claim 23, Albaum and Edelson failed to teach, wherein the medication specific labels for the medication includes

information about a level of potassium in the intravenous solution calculated using flame photometry. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the medication specific labels for the medication include information about a level of potassium in the intravenous solution calculated using flame photometry and to modify in Albaum because such a modification would allow Albaum to have a major intracellular action that is widely distributed in the body in muscle tissue, nerve tissue, blood cells, and plasma which is filtered in the glomerulus, absorbed in the proximal tubule and finally excreted by exchange for sodium in the distal tubule. The reliability depends on the proper maintenance of the flame photometer and the salient features. If low serum potassium values are observed due to low intake of dietary potassium over a period of time or increased loss through kidney, vomiting or diarrhea and increased secretion of adrenal steroids or some diuretics that promote the loss of potassium a flame photometer (digital flame photometer) for simultaneous measurement is useful in these medical conditions.

With respect to claim 24, Albaum teaches, the pharmacy client system of claim 23 wherein the modifications to the ingredients of the medication includes modifications to caloric content of the medication (col. 10, lines 17-43).

With respect to claim 25, this dependent claim is rejected for the similar rationale given above for claim 24.

With respect to claim 26, Albaum and Edelson failed to teach, wherein the modifications to the ingredients of the medication includes modifications to electrolytes in the medication. Official Notice is taken that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the modifications to the ingredients of the medication include modifications to electrolytes in the medication because such a modification in Albaum would allow Albaum to have substances that dissociate into two or more ions, to some extent, in water.

With respect to claim 27, this dependent claim is rejected for the similar rationale as given above for claim 26.

Response to Arguments

6. Applicants' arguments filed 12/15/03 have been fully considered but the following arguments are not considered to be persuasive.

Argument no. 1: Applicants' argue regarding claims 8 and 9: The action fails to cite any objective evidence that such knowledge actually exists or is instant and unquestionable has been considered but is not persuasive. Response: The evidence is in the On-Line Medical Dictionary reference listed in the prior art made of record in the Office Action of 09/10/03 which Applicants' are respectfully requested to read.

Argument no. 2: Applicants' argue regarding claims 11-13: This argument is addressed in the response above to Argument no. 1. Therefore, it is unnecessary to address the argument again.

In conclusion: The other arguments are considered "moot" in view of the new ground(s) of rejection above.

The motivation has been provided in the because statement and a suggestion/ motivation need not be expressly stated in one or all of the references used to show obviousness. *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1025, 226 USPQ 881, 886 (Fed. Cir. 1985); *In re Sheckler*, 438 F.2d 999, 1001, 168 USPQ 716, 717 (CCPA 1971). It is assumed that every reference relies to some extent on the knowledge of persons skilled in the art to complement that which is disclosed therein. Further, the skilled artisan is presumed to know something more about the

art than only what is disclosed in the applied reference. In other words, the person having ordinary skill in the art has a level of knowledge apart from the content of the references. *In re Bode*, 550 F.2d 656, 660, 193 USPQ 12, 16 (CCPA 1977); *In re Jacoby*, 309 F.2d 513, 516, 135 USPQ 317, 319 (CCPA 1962). A conclusion of obviousness is established "from common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference." *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

In this rejection of claim 1 and others, for example under Section 103 (a) of Title 35 of the United States Code, the Examiner carefully drew up a correspondence between the Applicants' claimed limitations and one or more referenced passages in the Edelson, Mayaud, Evans, and Albaum references, what is well known in the art, and what is known to one having ordinary skill in the art (the skilled artisan). The Examiner is entitled to give claim limitations their broadest reasonable interpretation in light of the Specification (see below*):*

2111 Claim Interpretation; Broadest Reasonable Interpretation [R-1]

>CLAIMS MUST BE GIVEN THEIR BROADEST REASONABLE INTERPRETATION

During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the

examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater, 162 USPQ 541,550-51 (CCPA 1969).<

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure.

Cupps et al (US 5,991,739) disclosed an online order method and apparatus.

Inquiries

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ella Colbert whose telephone number is 703-308-7064. The examiner can normally be reached on Monday-Thursday from 6:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin can be reached on 703-308-1038. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/E. Colbert
March 3, 2004